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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,029	12/02/2003	Joan D. Leonard	12780/102	4719

26646 7590 09/21/2007
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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

NOTIFICATION DATE	DELIVERY MODE
09/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@kenyon.com

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/726,029	Applicant(s) LEONARD ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 August 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *23 August 2007*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *21-46 and 48-61*.
   Claim(s) withdrawn from consideration: *NONE*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see advisory attachment.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: Advisory attachment.

MF

Advisory Attachment

1. This Office Action is responsive to Applicant's response filed August 23, 2007.

Rejections Maintained

The rejection is reiterated below:

2. The rejection under 35 U.S.C. 112, first paragraph (new matter) is maintained for claims 21-46 and 48-61 for the reasons set forth on pages 3-4, paragraph 3 of the Final Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-46 and 48-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.* The amendment filed December 18, 2006 introduces new matter into the claims.

The claims have been amended to recite, "...such that the number or percentage of bovine animals that show clinical symptoms of mastitis is less after such administering than before such administering...". 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant's amendment introduces "new matter" that is not supported by the original disclosure. The specification fails to show the claim limitation "a reduction in the number or percentage of bovine animals that show clinical symptoms of mastitis is less after such administering than before such administering". Applicant has failed to direct the Examiner as to where in the instant specification the support for this amendment is specifically shown or implied. In Applicant's response and marks (filed December 18, 2006) Applicant refers to incidence as a reduction in the number or percentage of cows showing clinical symptoms of mastitis after vaccination as compared to before vaccination. Applicant points to page 19, lines 17-31 of the specification to support this conclusion. The results on page 19 measure efficacy of the vaccine. There is no mention of symptoms of disease or the percentage of symptoms reduced. The

Examiner has reviewed the instant specification and has failed to find the support for the amendment. Applicant is required to cancel the new matter in the reply to this Office Action.

Applicant's Arguments

Applicant urges that a written description need not describe the subject matter claimed in the same words as are used in the claims. Applicant urges that the instant specification provides written description for the amendment filed December 14, 2006 which amended the claims to recite the phrase "such that the number or percentage of bovine animals that show clinical symptoms of mastitis is less after administering than before administering".

Applicant urges that the specification describes administration of the recited vaccine to bovine animals followed by a description of such beneficial effects of the vaccine as reduction in levels of infection, lack of clinical mastitis event and lack of confirmed cases of mastitis in vaccinated animals. Applicant urges that the instant specification states that the vaccine decreases the effect of *M. bovis* infections on milk production, weight gains and animal health. Applicant refers to pages 19-23 of the instant specification that discloses field evaluations of the bovine animals. Applicant asserts that they are in possession of the claimed subject matter and the specification supports the phrase " such that the number or percentage of bovine animals that show clinical symptoms of mastitis is less after administering than before administering".

Examiner's Response to Applicant

Applicant's arguments filed August 23, 2007 have been fully considered but they are not persuasive.

It is the Examiner's position that the amendment filed December 14, 2006 introduces new matter. The instant specification merely shows that after administration of the vaccine used in the claimed method bovine positive for *Mycoplasma bovis* infections had decreased (page 19 of the specification). The instant specification discloses that milk samples were taken from cows and screened (page 20 of the specification). Page 22 of the instant specification disclose that it is believed that vaccinated animals performed well as measured by days to market and rate of gain. However, there is no disclosure in the instant specification that shows that a reduced number or percentage of bovine animals *show less clinical symptoms of mastitis* after administration of the vaccine than before administration of the vaccine. The instant specification merely discloses *a reduction of animals that do not have mastitis*. In other words, the specification discloses the number or percentage of animals protected from disease after they have been administered the vaccine used in the claimed method. The specification is silent to the number animals that *have symptoms of mastitis* but do not have mastitis. It should be noted that the phrase symptom of disease is defined as "an indication of an undesirable situation". However, as it relates to the claimed method, a symptom of mastitis (an indicator) can be reduced and the animals still have mastitis. This situation is also encompassed by the claimed invention. It should be remembered

that the claimed invention encompasses animals that have reduced symptoms as well as animals that do not have mastitis. The art recognizes symptoms of mastitis as animals with swollen utters or animals that are low milk producers to name a few. The specification does not provide data from animals that have the before mentioned symptoms of mastitis. Additionally, the instant specification does not teach or disclose what constitutes a level of reduction such that the incidence is reduced.

In view of all of the above, this rejection is maintained.

3. The rejection under 35 U.S.C. 112, first second is maintained for claims 21-46 and 48-61 for the reasons set forth on pages 4-5, paragraph 4 of the Final Office Action.

The rejection is reiterated below:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-46 and 48-61 recite "whereby the incidence of mastitis in the bovine animals is reduced such that the number or percentage of bovine animals that show clinical symptoms of mastitis is less after such administering than before such administering...". It is unclear as to what the Applicant is referring? What clinical symptoms are reduced? Does a reduction in clinical symptoms necessarily mean that incidence of mastitis is reduced? A symptom of a disease or disorder can be reduced and the subject still has the disease or disorder. The Clarification and/or correction is required.

Applicant's Arguments

Applicant urges that the word "symptom" is common and the meaning is well-understood. Applicant urges that the instant specification provides examples of symptoms of mastitis of animals after immunization as compared to before

immunization. Applicant assert that a reduction of clinical symptoms necessarily means that the incidence of mastitis reduced. Applicant urges that the Examiner's statement that a symptom of a disease or a disorder can be reduced and the subject still have the disease or disorder is not relevant to the claimed invention.

Examiner's Response to Applicant's Arguments

It is the Examiner position that a reduction is symptoms does not necessarily mean that the incidence of mastitis is reduced. The Examiner agrees that the meaning of the term "symptom" is well understood. It should be remembered that a symptom of disease is defined as "an indication of an undesirable situation". However, as it relates to the claimed method, a symptom of mastitis (an indicator) can be reduced and the animals still have mastitis. This situation is also encompassed by the claimed invention. It is unclear as to what clinical symptoms Applicant is referring. It is also unclear as to what constitutes a level of reduction such that the incidence is reduced.

In view of all of the above, this rejection is maintained.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vanessa L. Ford
Biotechnology Patent Examiner
September 11, 2007

NITA MINNIFIELD
PRIMARY EXAMINER
9-14-07